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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,219	03/19/2004	Sarita Chaudhary	058187-0109	6099

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FOLEY AND LARDNER LLP
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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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01/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,219	Applicant(s) CHAUDHARY ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-22, 25-35, 68-70 and 72-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-22, 25-70 and 72-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed on 31 October 2007.
2. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4. Applicants' election with traverse of Group I, claims 1-35 and 63-70 and SEQ ID NO: 6 in the reply filed on 21 February 2007 is acknowledged. The traversal is on the ground(s) that the inventions are related as combination/subcombination and not as product and process of using (page 10 of the response filed on 11 October 2006). This is not found persuasive because the promoter sequences are only related as combination/subcombination in respect to a flax plant, the isolated nucleic acid of Group II is not a subcombination of a plant other than flax and thus is interpreted as an isolated product and Group I is related to Group II as a process of using the product. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

5. Claims 18 and 72-74 are objected to because of the following informalities: The instant claims are directed to non-elected sequences. Appropriate correction is required.

Applicants argue that they provisionally elected SEQ ID NO: 6, but Applicants maintain that the Restriction Requirement was improper. Applicants argue that in view

of generic claim 1, the Restriction Requirement falls squarely under an example of an *improper* restriction recently published with the proposed rules for Examination of Patent Applications That Include Claims Containing Alternative Claim Language, 72 Fed. Reg. 44,992 - 5,001 (Aug. 10, 2007) (page 12 of the Remarks). This argument is not found to be persuasive for the reasons of record. Applicants have not petitioned the restriction of record.

Claim Rejections - 35 USC § 112

6. Claims 18 and 70 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 May 2007. Applicant's arguments filed 31 October 2007 have been fully considered but they are not persuasive.

Claim 18 is indefinite because it recites at lines 5-6 "a nucleic acid sequence that is complementary" in limiting the promoter used in the method of claim 1, yet it is unclear how a complementary sequence of a promoter would function in the method of claim 1. Hence, the metes and bounds of the claim are unclear. Applicants argue that they believe the present version of claim 18 avoids the PTO's concerns and therefore request that the rejection be withdrawn (page 13 of the Remarks). This is not found to be persuasive because the claim remains directed to a method of using an antisense of a promoter sequence at 18(b). Said claim also recited "complementary complementary" which appears to be a typographical error.

Claim 70 is indefinite because it is unclear if the claimed plant seed comprises the chimeric nucleic acid used in the method of claim 1. Hence, the metes and bounds of the claim are unclear. Applicants argue that it was clear at the time of filing that a plant seed obtained from a plant and prepared according to the method of claim 1 would comprise the chimeric nucleic acid sequence, as the chimeric nucleic acid sequence is introduced into the plant cell and expressed in seed (page 13 of the Remarks). This is not found to be persuasive because T0 transgenic plants would produce progeny without the "nucleic acid sequence of interest". This is a fact well known in the instant art.

Claims 18 and 72-74 are indefinite because, Applicants teach at page 8, line 26 that the ABRE sequence consists of (G/C/T)ACGT(G/T)GC, but SEQ ID NO: 6 does not comprise this ABRE sequence, Applicants teach a "G box" in Figure 3-1 which has the sequence CACGTGTA. Hence, the metes and bounds of the claims are unclear because SEQ ID NO: 6 does not appear to comprise the required structure.

7. Claims 1-4, 7-22, 25-35 and 67-70 remain rejected and claims 72-74 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 May 2007. Applicant's arguments filed 31 October 2007 have been fully considered but they are not persuasive.

Applicants argue that independent claims 1, 19, and 68-69 are presently amended to specify that the seed-specific promoter comprises an RY repeat and an ABRE promoter element. Applicants argue that the present application discloses four seed-specific promoters that contain both an RY repeat and an ABRE promoter element, the nucleic acid sequences of the four promoters are provided in the application in SEQ ID NO:1, SEQ ID NO:4, SEQ ID NO:6, and SEQ ID NO:8 (page 14, 4th paragraph of the Remarks). Applicants argue that the as-filed specification describes a representative number of nucleotide sequences (e.g. SEQ ID NOs: 1, 4, 6, and 8) as well as the structural features common to the members of the genus (e.g. an RY repeat and ABRE promoter element) for the seed-specific promoters defined in the claims (page 15, 1st paragraph of the Remarks). These arguments are not found to be persuasive. Applicants outline the teachings of the art as it is directed to an RY element and an ABRE element at page 8 of the instant specification. The art teaches that an RY element is a repeat octamer of CATGCATG (see Reidt *et al* 2000, page 402, right column; and Bobb *et al* 1997, page 643, right column, second to last paragraph). In instant Figure 3-1 (SEQ ID NO: 6), Applicants refer in Figure 3-1 to an RY element as having the sequence [C]ATGAATA and a seed-specific element CATGCA, and at page 8, line 9 of the specification Applicants refer to an RY element as CATGCA. Hence, it does not appear from Applicants' teachings or that of the prior art that the promoter of nucleotides 1-417 of SEQ ID NO: 6 describe a promoter comprising an RY repeat promoter element. At page 8, lines 19-24 of the instant specification, Applicants state that "As used herein, the abscisic acid responsive element (ABRE) is defined as a

promoter element having a sequence of 8-10 base pairs with a core sequence of ACGT in accordance with the consensus sequence for ABRE as defined by Izawa *et al.* (1993) J. Mol. Biol. 14:61-72 and Shen and Ho (1995) Plant Cell 7:295-307". The Examiner could not find the Izawa *et al.* 1993 reference, and said reference has not been made of record by Applicants. Shen *et al.* (1995) teach that an ABRE consists of a G-box (GCCACGTACA), and a novel coupling element, CE1 (TGCCACCGG) (see the abstract on page 295). Shen *et al.* (1995) teach G-box sequences are necessary but not sufficient for ABA response. Applicants do not appear to describe a CE1 coupling element in the promoter region of SEQ ID NO: 6. Hobo *et al.*, referenced in the specification by Applicants, identified the ABRE sequence to be (G/C/T)ACGT(G/T)GC (page 15348, left column, 1st paragraph of the article). While the sequence described in SEQ ID NO: 6 (Figure 3) comprises a G-box element, it does not appear to comprise an ABRE promoter element within the understanding of the art. The issue of written description is a finding of fact, had Applicant described the invention such that one skilled in the art would have recognized that Applicant had possession of the invention as claimed. Given the evidence outlined above, it remains the Examiner's opinion that Applicants had not adequately described the invention as broadly claimed.

Applicants argue that applying the PTO's own standards to the instant invention, a conclusion that the present claim 18 satisfies the written-description requirement. Applicants argue that claim 18 recites specific *structural and functional* language characterizing the claimed polynucleotide sequences. Applicants argue that they are entitled to sequences that hybridize to a nucleic acid of SEQ ID NOS: 1, 4, 6 and 8

under stringent hybridization conditions, and claim 18 has been amended to recite sequences that hybridize to a specified sequence under stringent hybridization conditions (paragraph spanning pages 15-16 of the Remarks). These arguments are not found to be persuasive. The referenced example in the PTO guidelines cited by Applicants on page 15 of the Remarks is directed to isolating protein coding sequences using highly stringent hybridization conditions, not promoters. In addition, all of the limitations of claim 1, from which claim 18 depends, are read into claim 18, and the issue of written description is addressed above. Applicants provide no evidence that what Applicants assert are species of a claimed genus would hybridize one to the other under the recited conditions.

8. Claims 1-4, 7-22, 25-35 and 67-70 remain rejected and claims 72-74 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of using an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-417 of SEQ ID NO: 6 having seed-preferred promoter activity and a transgenic plant transformed therewith, does not reasonably provide enablement for a genus of seed-specific promoters obtained from flax comprising an RY repeat and an ABRE promoter element or an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 May 2007. Applicant's

arguments filed 31 October 2007 have been fully considered but they are not persuasive.

The reference to SEQ ID NO: 8 in the previous Office action was a typographical error and should have referred to SEQ ID NO: 6.

Applicants argue that the independent claims now recite that the seed-specific promoter comprises an RY repeat and an ABRE promoter element. Applicants argue that they have provided four examples of seed-specific promoters that comprise these elements. Applicants argue that they have taught how to make and use the genus of seed-specific promoters recited in the instant claims (paragraph spanning pages 16-17 of the Remarks). Applicants argue that with respect to sequences that hybridize under stringent conditions to recited sequences, the application as filed provides sufficient guidance to enable one of skill in the art to prepare such sequences. Applicants argue that only a routine amount of work would be required for someone skilled in the art to design suitable sequences and assess their hybridization under the recited stringent hybridization conditions (page 17, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. The teachings of the art are outlined above as it relates to RY repeat and ABRE promoter element.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicants outline the teachings of the art as it is directed to an RY element and an ABRE element at page 8 of the instant specification. The art teaches that an RY element is a repeat octamer of CATGCATG (see Reidt *et al* 2000, page 402, right column; and Bobb *et al* 1997, page 643, right column, second to last paragraph). In instant Figure 3-1 (SEQ ID NO: 6), Applicants refer in Figure 3-1 to an RY element as having the sequence [C]ATGAATA and a seed-specific element CATGCA, and at page 8, line 9 of the specification Applicants refer to an RY element as CATGCA. Hence, it does not appear from Applicants' teachings or that of the prior art that the promoter of nucleotides 1-417 of SEQ ID NO: 6 describe a promoter comprising an RY repeat promoter element. At page 8, lines 19-24 of the instant specification, Applicants state that "As used herein, the abscisic acid responsive element (ABRE) is defined as a promoter element having a sequence of 8-10 base pairs with a core sequence of ACGT in accordance with the consensus sequence for ABRE as defined by Izawa *et al.* (1993) J. Mol. Biol. 14:61-72 and Shen and Ho (1995) Plant Cell 7:295-307". The Examiner could not find the Izawa *et al* 1993 reference, and said reference has not been made of record by Applicants. Shen *et al* (1995) teach that an ABRE consists of a G-box (GCCACGTACA), and a novel coupling element, CE1 (TGCCACCGG) (see the abstract on page 295). Shen *et al* (1995) teach G-box sequences are necessary but not sufficient for ABA response. Applicants do not appear to describe a CE1 coupling element in the promoter region of SEQ ID NO: 6. Hobo *et al*, referenced in the

specification by Applicants, identified the ABRE sequence to be (G/C/T)ACGT(G/T)GC (page 15348, left column, 1st paragraph of the article). While the sequence described in SEQ ID NO: 6 (Figure 3) comprises a G-box element, it does not appear to comprise an ABRE promoter element within the understanding of the art. Given these facts, it does not appear that Applicants have taught how to make and use seed-specific promoters obtained from flax comprising an RY repeat and an ABRE promoter element. It is unclear that using a polynucleotide comprising SEQ ID NO: 6, or its complement, one of skill in the art at the time of Applicants' invention could have isolated seed-specific promoters obtained from flax comprising an RY repeat and an ABRE promoter element.

Double Patenting

9. Claim 18 remains rejected and claims 72-74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,777,591. Although the conflicting claims are not identical, they are not patentably distinct from each other because the promoter of SEQ ID NO: 8 in the issued patent, claim 1, is asserted by Applicants to comprise the promoter elements of the instant claim 1. Applicants state that they respectfully defer this issue until the application is otherwise in condition for allowance (page 18 of the Remarks). Applicants' statement is noted, but the rejection is maintained.

Conclusion

10. No claims are allowed.

11. The claims, as currently amended, are free of the prior art.

Application/Control Number:
10/804,219
Art Unit: 1638

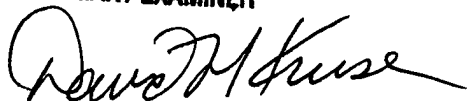
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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
9 January 2008

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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